REMARKS

I. Status of the Claims

Prior to the present paper, claims 1-32 and 43-57 were pending. Claim 43 is allowed and claim 32 is allowable, but "objected to" as being dependent on a rejected base claim. As claim 43 is allowed, claims 45-48, which each depend on claim 43, are also allowed.

Presently, claims 4-10, 13, 14, 16, 18, 19, 25-28, 32, 43, 44, 50, 53 and 54 have been amended without prejudice, to implement the agreement on allowance from the recent interviews. Claims 1-3, 11, 12, 20-24, 49 and 51 have also been canceled without prejudice. No claims have been added. Claims 4-10, 13-19, 25-32, 43-48, 50 and 52-57 are therefore in the case. According to 37 C.F.R. § 1.121(c), a copy of the pending claims is provided in the amendment section.

II. Support for the Claims

Support for the amended claims exists in the pending claims and throughout the original application as filed.

The main independent claim in the case is now claim 52, which is unamended, and in which the targeting agent-therapeutic agent of the claimed kit comprises a targeting agent that binds to phosphatidylethanolamine.

Claims 4-10, 13, 14, 16, 18, 19 and 25-28 and 32 have each been revised to accord with claim 52, and are supported thereby. In addition, claim 32 has been revised to specify that the claimed kit "further" comprises the recited targeting agent-detectable agent construct.

Independent claim 43, which was allowed, has voluntarily been revised to specify that the targeting agent binds to phosphatidylethanolamine, thereby matching claim 52. Claim 44 has been revised to accord with claim 43.

Claim 50 has been revised to depend from claim 52.

Independent claim 53 has also been revised to specify that the targeting agent binds to phosphatidylethanolamine, thereby matching claim 52. Claim 54 has been revised to accord with claim 53.

It will therefore be understood that no new matter is included within the new claims.

III. Entry of Amendments

The present amendments are entitled to entry as being specifically solicited by the Office.

IV. Applicants' Interview Summaries

Applicants filed an Appeal Brief in the present application on July 29, 2004. After filing the Appeal Brief, a number of telephone interviews were held between Applicants' undersigned representative and Examiner Sharareh.

A personal interview was also arranged and held at the Office on November 18, 2004, which included Applicants' undersigned representative, Examiner Sharareh, SPE Padmanabhan and practice specialist Caputa. Applicants appreciate the Examiners' time and the productive discussions. Although agreement was not reached during the personal interview, it was agreed that claim 52 was a good candidate for allowance.

Following the personal interview, further telephone interviews have been held between Applicants' undersigned representative and Examiner Sharareh. During these interviews, it was agreed that claim 52 was allowed and that most claims in the case could be allowed by revising to depend from claim 52. Applicants prepared a draft of the revised claims, which was forward to Examiner Sharareh via facsimile on December 07, 2004.

The claims submitted as a draft on December 07, 2004 are presently being made of record. Applicants' choice to proceed mainly on the basis of claim 52 is made without

acquiescing in any way with any outstanding rejection, but rather is being taken simply to progress certain claims to issue after a lengthy examination.

In a telephone interview held between Applicants' undersigned representative and Examiner Sharareh on December 22, 2004, Examiner Sharareh requested a Terminal Disclaimer over U.S. Patent No. 6,818,213 (application Serial No. 09/351,598). Such a disclaimer and the required fee are presently submitted.

During the telephone interviews, Examiner Sharareh raised the issue of written description support for the invention under 35 U.S.C. § 112, first paragraph. Applicants pointed out that the original claim terms "targeting agent", "aminophospholipid binding protein" and "anti-aminophospholipid antibody" *prima facie* comply with the written description requirement, as they are directed to kits comprising compositions already patented. Note, in particular, U.S. Patent No. 6,818,213, raised by the examiner in a double-patenting context and for which a Terminal Disclaimer is presently submitted. Also, two other U.S. patents have issued, U.S. Patent Nos. 6,312,694 and 6,783,760, claiming *in vivo* methods of using the presently claimed kits.

The specification also describes aminophospholipid targeting agents and binding proteins at pages 4-36, 68-76, 89-117, 122-123, 146-151 (targeting agent-detectable agent constructs), 223-235 and Example XIII (page 199). In U.S. Patent No. 6,818,213 and in the present application (see fax of April 21, 2004), a declaration is of record with data showing successful tumor treatment *in vivo* using a targeting agent-therapeutic agent construct in which the targeting agent is a binding protein rather than an antibody.

As to antibodies, the specification describes anti-aminophospholipid antibodies at pages 4-36, 54-69, 89-117, 122-132, 223-235, Example VIII (pages 190-192), Example XI (pages 194-197), Example XII (pages 197-198) and Example XIV (pages 199-203), including

the references incorporated therein. For example, the specification includes data showing successful tumor treatment *in vivo* using the anti-aminophospholipid antibody termed 3SB. Samples of the 3SB antibody were obtained by the present inventors from Dr. Neal S. Rote of Wright State University. Dr. Rote is not a joint inventor on the present application, which was documented in the same declaration filed in U.S. Patent No. 6,818,213 (09/351,598), and submitted in the present application via facsimile on April 21, 2004.

After the telephone interview of December 22, 2004, Applicants forwarded via facsimile an additional copy of this declaration, and an additional copy of Umeda *et al.*, *J. Immunol.*, 143:2273-2279, 1989 ("Umeda"), an exemplary antibody paper incorporated by reference into the specification. Umeda had also been submitted earlier in the present application, with the Information Disclosure Statement (IDS) filed September 21, 1999 (Umeda is IDS ref. C29).

According to a telephone message from Examiner Sharareh of January 11, 2005, it is not clear whether the facsimile copy of the declaration from U.S. Patent No. 6,818,213 is sufficient. Accordingly, additional copies of the declaration and all exhibits are enclosed herewith as a precaution.

The present response is being submitted at the express request of the Office. As there is no outstanding deadline, no fees are required (other than the fee for the Terminal Disclaimer, which is enclosed). The response, Terminal Disclaimer and copy of the declaration from U.S. Patent No. 6,818,213 place the application in condition for allowance by implementing the steps requested by the Office.

V. Appeal Brief

As to the earlier rejections entered in the present application, Applicants respectfully refer to the Appeal Brief filed in the present application on July 29, 2004 and specifically